



**Cost Feasibility Analysis for Use of
National Average Drug Acquisition Cost (NADAC)
For Maryland Medicaid Pharmacy Reimbursement**

July 2014

Objective

The Maryland Department of Health and Mental Hygiene (DHMH) contracted Myers and Stauffer LC to study the feasibility of replacing its current pharmacy pricing methodology with the National Average Drug Acquisition Cost (NADAC). NADAC is a pricing reference file published by the Centers for Medicare & Medicaid Services (CMS) that is based upon average actual acquisition costs (AAC) of covered outpatient drugs collected from a monthly survey of retail community pharmacies across the United States.

Background

National application of AAC-based pharmacy reimbursement was championed by the National Association of State Medicaid Directors (NASMD) in its white paper titled "Post AWP Pharmacy Pricing and Reimbursement" that was published in 2010.¹ Among the recommendations presented in the white paper was the establishment of a single national price benchmark for pharmacy reimbursement based on average drug acquisition costs. Such a benchmark would provide state Medicaid agencies with a more accurate and responsive pricing methodology for covered outpatient drugs since it would be based upon actual drug purchase experience. This approach to drug ingredient price determination not only provides greater accuracy and transparency in how drug prices are established, but it is also generally more resistant to manipulation. NASMD requested that CMS coordinate, develop, and support this benchmark. The Office of Inspector General (OIG) also provided a recommendation for CMS to "develop a national benchmark that accurately estimates acquisition cost and encourage States to consider it when determining Medicaid reimbursement for prescription drugs."²

Furthermore, in its Proposed Medicaid Pharmacy Outpatient Rule (CMS-2345-P) to amend 42 CFR part 447, subpart I published on February 2, 2012, CMS proposes to replace Estimated Acquisition Cost (EAC) with Actual Acquisition Cost as the basis for state Medicaid pharmacy ingredient cost reimbursement. Specifically, it states:

...we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, "estimated acquisition cost" with "actual acquisition cost" (AAC). We believe that changing this definition for the drug ingredient component of the reimbursement formula to AAC will be more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing...Therefore, in § 447.502, we propose to define actual acquisition cost as the agency's determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. (p. 5320-5321)

¹ American Medicaid Pharmacy Administrators Association and The National Association of Medicaid Directors. Post AWP Pharmacy Pricing and Reimbursement. June 2010.

² Department of Health and Human Services, Office of Inspector General. Replacing Average Wholesale Price: Medicaid Drug Payment Policy. OIG report no. OEI-03-11-00060. July 2011.

In addition, CMS suggests that the move from an estimated pricing methodology for ingredient drug pricing to one that is AAC-based will impact the previous balance of overall pharmacy reimbursement, thereby requiring states to concurrently re-evaluate the dispensing fee. This regulatory change corresponds with the recommendation of the NASMD and the OIG and is expected to soon be formally finalized in a final rule. Prior to the development of the NADAC, several State Medicaid programs had already instituted their own state-level AAC pharmacy reimbursement programs. Beginning with Alabama in 2008, these programs utilize an approach to collecting pharmacy acquisition costs through surveys of in-state Medicaid-participating providers. Each of these programs also modified their dispensing fees to reflect the results of a cost of dispensing survey simultaneously with the change in drug ingredient reimbursement.

DHMH currently utilizes a pharmacy reimbursement methodology that is based upon published compendia pricing. Brand drugs are reimbursed utilizing the lower of Average Wholesale Price (AWP) minus 12%, Direct Price (DP) plus 8%, Wholesale Acquisition Cost (WAC) plus 8%, or the pharmacy's submitted charges. Generic drugs utilize the lower of the same reimbursement rates as brand drugs with the additional comparators of the State Maximum Allowable Cost (SMAC) rate and the Federal Upper Limit (FUL). The Department utilizes different dispensing fees based upon whether the drug is a non-preferred brand drug (\$2.56 per claim) or generic drug or preferred brand (\$3.51 per claim) or whether the pharmacy is a nursing home (\$3.51 for non-preferred brand drugs, \$4.46 for generic drugs or preferred brand) or a home intravenous drug therapy provider (\$6.89 per claim).

Scope

In order to evaluate the replacement of the current Maryland Medicaid reimbursement methodology with a NADAC-based pharmacy reimbursement formula, it is necessary to perform an estimated fiscal impact analysis. In addition, Myers and Stauffer LC will provide technical considerations for DHMH with regards to the adoption of NADAC for reimbursement.

This evaluation consists of a point-in-time study using historical Maryland pharmacy utilization. Claims were recalculated using NADAC for drug ingredient reimbursement and a single dispensing fee of \$10.49, which was derived from results of a cost of dispensing study performed for DHMH in 2011. The analysis incorporated the impact of both a change in drug ingredient and dispensing fee reimbursement methodologies in compliance with the Proposed Rule.

Methodology

The analysis models the change from the current pharmacy reimbursement to a NADAC-based reimbursement and single dispensing fee that applies to all claims.

Data Sets

- Maryland pharmacy claims from 12/1/2012 through 2/28/2013, then annualized
- Includes retail pharmacy and nursing home pharmacy Point-of-Sale claims
- NADAC file published on 5/23/2013
- Published pricing data from 5/23/2013
- Current FUL rates, last updated on 10/26/2009
- Draft AMP-based FUL rates, last updated in February 2013

The following is a table that details the reimbursement methodologies utilized in this analysis.

Table 1: Current Reimbursement Methodology and NADAC-based Reimbursement Methodology

	Current Maryland Medicaid Pharmacy Reimbursement	Modeled NADAC Reimbursement
Brand Drugs	Lower of: <ul style="list-style-type: none"> EAC ¹ Usual and Customary Charge ² 	Lower of: <ul style="list-style-type: none"> NADAC WAC+0% if no NADAC Usual and Customary Charge ²
Generic Drugs	Lower of: <ul style="list-style-type: none"> EAC ¹ Maryland SMAC FUL Usual and Customary Charge ² 	Lower of: <ul style="list-style-type: none"> NADAC WAC+0% if no NADAC Usual and Customary Charge ²
Dispensing Fee	\$3.51 for generics and brands on PDL ⁴ \$2.56 for brands not on PDL \$4.46 for Nursing home generic and brands on PDL \$3.51 for Nursing home brands not on PDL	\$10.49

¹EAC = lower of AWP - 12%, DP+8%, or WAC+8%

²Units for Usual and Customary Charge claims were utilized in the analyses performed

³Represents mean weighted by Medicaid volume

⁴PDL = Preferred Drug List

Observations / Findings

A. Fiscal Impact of NADAC Pricing Methodology without FULs (refer to Tables 6, 7, and 8 in the Appendix for Analysis Details)

- 1) Ingredient Cost: Overall, replacement of Maryland's current pharmacy pricing methodology with NADAC would result in a **decrease** in annual spend on drug ingredient costs of an **estimated -\$20.9M (State and Federal)**. This is further delineated as follows:
 - a. Brand Drugs: Estimated decrease of -\$20.8M
 - b. Generic Drugs: Estimated increase of +\$134K
 - c. OTC Insulin: Estimated decrease of -\$202K
- 2) Dispensing Fee: A corresponding change in the current dispensing fees listed above to \$10.49 for all drugs would result in an **increase** in annual spend by an **estimated +\$22.3M (State and Federal)**.
- 3) **Net Fiscal Impact: The net annual fiscal impact with the modeled change to NADAC reimbursement is estimated to increase annual spend by +\$1.4M (State and Federal).**

B. Fiscal Impact of AMP-Based FULs within NADAC Pricing Methodology (refer to Table 9 in the Appendix for Analysis Details)

Ingredient Cost: Overall, inclusion of AMP-based FULs in a NADAC pharmacy pricing methodology would result in a **decrease** in annual spend on drug ingredient costs.

- 1) Monthly AMP-based FULs: Estimated decrease of -\$2.1M compared to NADAC pricing without FULs
- 2) Three-month Rolling AMP-based FULs: Estimated decrease of -\$2.2M compared to NADAC pricing without FULs

C. NADAC Rate Coverage (refer to Table 10 in the Appendix for Analysis Details)

Although there will be a NADAC rate for the large majority of a state's drug claims, not every drug will have a NADAC rate. Examples of drugs that might not have a NADAC at the time of a claim are new drugs, drugs dispensed primarily through a specialty pharmacy, and low utilized drugs. A state will need to develop an alternative pricing strategy for drugs without a NADAC rate.

When comparing availability of NADAC rates to historical Maryland Medicaid drug utilization, the majority of claims adjudicated through the point-of-sale system for Maryland Medicaid patients had an associated NADAC rate (98.7%). In cases where a NADAC was not available, WAC+0% was utilized in the model. The use of WAC+0% accounted for 1.2% of claims. The number of claims for drugs without a NADAC or WAC was minimal (0.1%).

D. Differential Dispensing Fee for Nursing Home (NH) Pharmacies

In its current reimbursement, Maryland offers a higher dispensing fee for NH claims. Based upon the intent of the proposed rule, a state plan with a differential dispensing fee for NH claims would be considered if the state can provide supporting evidence that a different dispensing fee is warranted. For this examination, several higher dispensing fees were modeled for nursing home claims to estimate the fiscal impact of maintaining a differential dispensing fee for nursing home pharmacy claims.

Table 2: Sensitivity Analysis of Potential Nursing Home Dispensing Fee Options

Dispensing Fee	Compared to Non NH Pharmacy Claims (per claim)	Estimated Annual Fiscal Impact
\$10.49	-	-
\$11.49	+\$1	+\$234,288
\$12.49	+\$2	+\$468,576

E. Differential Dispensing Fee for Non-Preferred Drugs

In its current reimbursement, Maryland differentiates dispensing fees for preferred or non-preferred products. Based upon the intent of the proposed rule, a state plan that proposes a lower dispensing fee for non-preferred products will not be considered since the cost to dispense non-preferred products is not less than the cost to dispense preferred products.

Discussion

The results of this analysis indicate that complying with the rule changes by transitioning from current reimbursement to NADAC without FULs while implementing a single dispensing fee of \$10.49 for all claims is estimated to *increase* the overall Maryland Medicaid annual pharmacy spend by approximately +\$1.4M (State and Federal). The driving factor for this additional spend is the cost of increasing the dispensing fee to reflect the results of a recent cost of dispensing survey.

Impact on Drug Ingredient Spend

As expected, the spend on brand drug ingredient costs *decreased* when claims were recalculated using NADAC. An OIG study found that invoice prices for brand drugs were 18% less than AWP on average.³ In comparison, the current EAC used by DHMH utilizes a reimbursement rate of AWP-12%, DP+8%, or WAC+8% for brand drugs, which provides reimbursement higher than what the OIG found drug invoice prices were. While the estimated spend on generic drug ingredient costs would increase slightly, the difference in generic drug ingredient reimbursement (+\$134,000 for the year) can be considered cost neutral. Likewise, the fiscal change in OTC insulin spend (approximately -\$202,000) can be considered cost neutral. Due to brand drugs, the overall net spend on drug ingredient costs would decrease substantially if using NADAC for reimbursement.

In comparing NADAC rates to Maryland Medicaid pharmacy claims, the large majority of drug claims will have an associated NADAC. For those drugs without a NADAC rate, the State will need to accommodate an alternative pricing methodology. The State may choose to further evaluate the pricing that it utilizes for these claims for appropriateness to achieve the Department's objectives. This issue is discussed in more detail in the Considerations for NADAC Reimbursement section.

Impact of Federal Upper Limit Rates

There are three FUL rates that are included in this analysis: Current FUL rates, Draft monthly AMP-based FUL rates, and Draft 3-month Rolling Average AMP-based FUL rates. The current FUL rates have not been updated since 2009. However, these rates are currently in use by Maryland and other state Medicaid agencies. The current FUL rates were included in the current reimbursement model to reflect current pharmacy reimbursement.

The monthly AMP-based FUL rates are updated monthly based upon the Average Manufacturer Price (AMP) reported to CMS by drug manufacturers. The 3-month Rolling Average AMP-based FULs are also updated monthly but incorporates a smoothing technique to reduce the impact of month-to-month fluctuations in reported AMP data. This smoothing technique consists of the weighted average of the current and two previous draft monthly AMP-based FUL rates. These rates are currently in draft status and unavailable for use in reimbursement. Although an Informational Bulletin published by CMS in November 2013 indicated the intent to finalize these FUL rates in July 2014, CMS indicated in June 2014 that the AMP-based FULs would not be finalized until further notice. As reported in the findings above, use of the either AMP-based FULs would result in a decrease in drug ingredient spend when used to replace the current FULs in current reimbursement or when used with the NADAC pricing methodology.

³ Department of Health and Human Services, Office of Inspector General. Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices. OIG report no. A-06-11-0002. October 2011.

Although still in draft form, some analyses have been performed on the impact of the AMP-based FULs. The U.S. Government Accountability Office (GAO) published a report on their findings comparing the AMP-based FULs to the NADAC.⁴ The GAO reported nearly half of the AMP-based FUL rates as lower than the corresponding NADAC rates within the sample tested. Likewise, nearly half of the FUL rates were higher than the corresponding NADAC rates. In its Informational Bulletin, CMS indicated “we expect that the use of the NADAC pricing could allow states to meet the FULs aggregate upper limit, and states may want to consider the use of the NADAC.” Consideration needs to be given to the inclusion or exclusion of AMP-based FUL rates in future pharmacy reimbursement, particularly with respect to meeting the FUL aggregate upper limit requirement.

Impact on Dispensing Fee

The increase in modeled overall Medicaid pharmacy spend is due to a concurrent increase in the dispensing fee that supersedes the savings associated with the adoption of NADAC for drug ingredient pricing. Currently, the model utilizes a projected dispensing fee of \$10.49 for all claims. This dispensing fee is based upon the median cost of dispensing weighted by Medicaid volume. It is comparable to those utilized by other Medicaid programs that utilize an AAC reimbursement plus a single dispensing fee calculated as the mean cost of dispensing weighted by Medicaid volume. Other States that utilize AAC pricing with a single dispensing fee range from \$10.12 to \$10.64.⁵ Utilizing a dispensing fee that is more in line with the ones currently used by other AAC programs could modify the net fiscal impact of a change in the dispensing fee. For example, a dispensing fee of \$10.00 would result in a net fiscal impact that is cost neutral (-\$0.2M State and Federal).

A dispensing fee based upon the median cost of dispensing weighted by Medicaid volume was selected instead of other options presented in the pharmacy dispensing cost analysis report due to its validity as a measure of central tendency. Therefore, for estimating the feasibility of using the NADAC for reimbursement, we chose the dispensing fee method that has precedence for CMS approval.

CMS has not provided official guidance with regard to its expectations of how a State should determine its professional dispensing fee. Common understanding is that CMS will allow States to perform a state-specific cost of dispensing survey, or utilize recently completed surveys from neighboring states. The dispensing fee used in this analysis is from a cost of dispensing survey performed specifically for DHMH of Maryland Medicaid-participating pharmacies. The cost of dispensing survey resulted in various options for selecting a dispensing fee that could be justified to CMS. Therefore, we recommend that the State revisit the results of its cost of dispensing survey to determine if another option is available to represent the cost of dispensing drugs while achieving the Department’s program objectives.

The Department expressed interest in examining differential dispensing fees for various pharmacy characteristics. One scenario was the provision of a higher dispensing fee for nursing home pharmacies. There were an estimated 235,000 pharmacy nursing home claims that paid a dispensing fee in a year. Therefore, any increase in the dispensing fee for nursing home pharmacies would be estimated to

⁴ United States Government Accountability Office. Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs. GAO report no. GAO-14-68. December 2013.

⁵ Refer to Appendix for list of States utilizing AAC-based reimbursement

impact approximately this many claims. CMS indicated that it would consider differential dispensing fees if evidence is provided to support the need for this difference.

Other scenarios examined were differential dispensing fees such as tiered dispensing fees based upon Medicaid prescription volume, based upon pharmacy urban or rural setting, or chain or independent affiliation, or preferred drug status. For representation of typical reimbursement methodologies, this analysis utilized the single dispensing fee model that is employed by the majority of Medicaid programs that utilize AAC reimbursement and did not consider tiered dispensing fees or those based upon pharmacy characteristics. Reimbursement based upon preferred drug list status that is not supported by evidence showing the differential costs for dispensing these drugs would not be considered by CMS.

Assumptions/Limitations

Several assumptions were made in designing this analysis. The current State MAC program was not used in the NADAC-based reimbursement model since it was assumed that the NADAC would replace the State MAC rates. Submitted charges were excluded from the analysis due to the complexity involved with limited benefit. The fiscal impact analyses of AMP-based FUL rates did not include consideration of multi-source brand products that may have been subjected to FUL reimbursement.

The analysis excluded NDCs for blood factors, nutritional products, durable medical equipment, prophylactic, and supply products. Analysis did not consider actual paid amounts associated with claims. Instead, units dispensed were repriced using the payment algorithms described in the Methodology section.

We utilized the most current quarter of Maryland pharmacy claims data that we had available, and multiplied the utilization and claims counts by four to annualize the results. We opted to use this approach rather than utilize the actual experience over 12 consecutive months, due to the potential to overestimate the fiscal impact of brand drugs that had lost market share to generic competition over the course of the year. The quarter of claims data utilized encompassed the cold and flu season, which addresses seasonal variations in drug utilization for the winter months. Variation in seasonal utilization may impact some of the results.

Conclusions

The fiscal impact of changing reimbursement from the current pharmacy reimbursement methodology to a NADAC-based methodology along with increasing the dispensing fee is estimated to result in a net cost for the State of approximately +\$1.4M annually (State and Federal dollars).

The NADAC represents one of the primary options for States to transition from EAC-based pricing to an AAC-based methodology, which is the direction that CMS has proposed for pharmacy reimbursement in its Medicaid rule. Although CMS has not indicated the timeline by which States will need to comply with the Rule, DHMH will already be in compliance with the directives by adopting the NADAC and adjusting its dispensing fee to reflect the results of a cost of dispensing study.

There are considerations that the State will need to make in order to fully implement the NADAC for reimbursement. These are described within the discussion below. A check list is included in the appendix that the State can use when addressing considerations for NADAC implementation.

The State will need to consider what additional maintenance services, such as receiving and addressing pharmacy inquiries regarding individual claims, developing an alternative pricing strategy for drugs without a NADAC (such as specialty drugs, new drugs or low utilized drugs), and assigning reimbursement rates for NDCs that are not identified on the NADAC rate file, it will need to account for when using the NADAC and whether they will require the assistance of a vendor. If a vendor is required, then an RFP will need to be drafted and funding secured.

Based on the results of this analysis, we conclude that **it is feasible for the State to adopt a reimbursement methodology using the NADAC** from a technical standpoint. From a fiscal standpoint, the Department would need to determine whether the net fiscal impact of this change, or other variations of the options discussed, will align with its pharmacy program objectives. This change would allow DHMH to be compliant with the Proposed Rule, the fiscal impact can be mitigated to cost neutral if a dispensing fee less than the one modeled could be utilized, and the stakeholders should be more willing to accept the change if it remains cost neutral or increases their reimbursement. CMS appears to understand that States will need time to implement the change so there do not appear to be feasibility issues due to timing of necessary claims system changes.

Our recommendation is to move forward with the steps to adopt NADAC for pharmacy reimbursement. The appendix of the report address considerations for NADAC implementation.

We look forward to discussing this report with you and assisting you with your decision-making process regarding use of the NADAC for pharmacy reimbursement.

APPENDIX

1. Considerations for NADAC Reimbursement
2. NADAC Reimbursement Checklist
3. Other State Medicaid Programs Utilizing Average Acquisition Cost Reimbursement
4. Analysis Details

1. Considerations for NADAC Reimbursement

The State will need to understand the considerations for utilizing the NADAC and prepare solutions for potential issues, as it will not be a simple replacement of a pricing reference file. The following section outlines these considerations.

Understanding NADAC

It is imperative that DHMH understand what the NADAC will and will not provide as a drug pricing benchmark. The following is a brief list of characteristics of NADAC that will bring perspective to the use of this pricing benchmark.

Table 3: Considerations for NADAC Reimbursement

Topic	AWP	NADAC	Considerations for NADAC Reimbursement
Coverage of NDCs	All	<ul style="list-style-type: none"> -Approximately 98% of DHMH covered drugs -Limited to CMS covered outpatient drugs -Excludes some specialty drugs 	Need alternative pricing methodology for claims for drugs without a NADAC rate
Comparison to current reimbursement	N/A	Reduced drug ingredient reimbursement	
Update frequency	Depends on manufacturer reporting	<ul style="list-style-type: none"> -Monthly brand and generic updates reflecting survey data -Weekly updates for brand NADACs reflecting changes in WAC or help desk inquiries 	NADAC has consistent reporting updates based upon drug pricing changes in the marketplace
Backdating rate changes	Yes	<ul style="list-style-type: none"> -Yes, for brand products to the extent that the NADAC effective date would be backdated to align with the change in published pricing effective date -No backdating for generic products 	Changes in NADAC will not be backdated by CMS. If the State wants to allow NADAC rate changes to be backdated for providers to reprocess claims, it will need to make arrangements .
Publication	Drug compendia	Drug compendia and CMS website	

Topic	AWP	NADAC	Considerations for NADAC Reimbursement
Pricing Level	Unique per NDC	Unique per drug group. Drug group delineations are based upon drug ingredients, strength, dosage form, route of administration, OTC/prescription status, package size (for particular groups), brand/generic status, and labeler (for particular groups). NDCs within the same drug group will receive the same NADAC rate.	NADAC rate assignment is similar to FUL and SMAC where NDCs from different labelers can share the same NADAC rate.
Provider support	None	CMS NADAC help desk	NADAC help desk will not address individual claims, only address changes in drug prices that will appear on future NADAC rate files. DHMH will need to maintain a help desk to address individual claims and other state-specific issues.
Reflective of drug acquisition costs	No	Yes	

For a more detailed explanation of the NADAC, CMS has provided a NADAC methodology document on its website (<http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html>).

NADAC is not available for every drug.

Since NADAC is based upon the drug purchase prices reported by retail community pharmacies, NADAC rates would only be available if pharmacies reported costs for these drugs. Drugs such as new products, low utilized products, and drugs not dispensed through the retail community pharmacy setting (such as some specialty drugs) will not have NADAC rates; therefore, DHMH will need to establish an alternative pricing methodology for adjudicating claims for these drugs.

Our recommendation is that the State utilize a WAC-based reimbursement approach for drugs without a NADAC rate. The WAC shares a close relationship to the drug acquisition cost for brand drugs. WAC does not bear a close relationship to generic drug costs.⁶ However, to allow claims to continue to process without interruption, we recommend use of WAC until a NADAC is assigned. This approach will necessitate accommodation of a provider support help desk to address claims for NDCs

⁶ Department of Health and Human Services, Office of Inspector General. Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices. OIG report no. A-06-11-0002. October 2011.

without a NADAC or a WAC rate, particularly for generic drugs which have a larger number of products without WACs.

Another option would be to collect acquisition costs on the State level and establish State -level AAC rates for drugs without a NADAC, or without a NADAC and WAC. This process would likely be more involved than a State Medicaid agency's staff is able to perform, therefore DHMH should consider hiring a contractor to maintain this aspect of the program change. Please refer to the section below for more detailed recommendations for this option.

Reimbursement Methodology

Based upon our experience with State-level AAC programs and our knowledge of the NADAC program, our recommended reimbursement methodology for Maryland Medicaid is as follows:

Table 4: Proposed Reimbursement Methodology for Pharmacy Drug Ingredients

	When NADAC is available	When NADAC is unavailable	When NADAC and WAC are unavailable
Brand Drugs	Lower of: <ul style="list-style-type: none"> NADAC + Dispensing Fee Usual and Customary Charge 	Lower of: <ul style="list-style-type: none"> WAC+0% + Dispensing Fee Usual and Customary Charge 	Pharmacy prompted to contact State or vendor for submission of acquisition costs
Generic Drugs	Lower of: <ul style="list-style-type: none"> NADAC + Dispensing Fee FUL + Dispensing Fee* Usual and Customary Charge 	Lower of: <ul style="list-style-type: none"> WAC+0% + Dispensing Fee FUL + Dispensing Fee* Usual and Customary Charge 	Pharmacy prompted to contact State or vendor for submission of acquisition costs

*CMS allows flexibility to simply meet the FUL in the aggregate. Levels at which final AMP-based FULs are established may impact the State's decision to use the FUL in claim adjudication.

NADAC file and claims payment system changes

The major drug compendia (including First DataBank, which DHMH utilizes) currently publish the NADAC rates; therefore, DHMH should not have to be concerned with downloading the weekly NADAC file from the CMS Medicaid website. However, DHMH will need to account for the time needed to program changes in the claims processing system. Although CMS has not indicated when they expect States to comply with the changes dictated in the Proposed Rule once it becomes final, the expectation is that CMS will allow some implementation time for States to draft and submit State Plan Amendments and coordinate reimbursement changes with their claims processors.

Policy Changes

As the State is aware, numerous process documents will need to be updated to reflect a change in reimbursement policy. These include the Medicaid State Plan, State Rule, and provider manual.

Timing of NADAC Availability

The NADAC rates are finalized and available for use. One State Medicaid agency currently utilizes NADAC rates for its pharmacy claims reimbursement (see Table 5). Although CMS has not provided

guidance with regards to a timeframe by which its covered outpatient drug proposed rule will become final or when States will need to comply with the Final Rule, DHMH will need to consider what decisions will be required to comply with the changes in the CMS Rule.

Pricing for Specialty Drugs

The CMS Proposed Rule does not differentiate between specialty drugs and non-specialty drugs when changing EAC to AAC for ingredient cost. As discussed earlier, specialty drugs that are not dispensed through retail community pharmacies will not have a NADAC rate. Therefore, DHMH should consider how to provide reimbursement for specialty drugs in such a way that reimbursement is in compliance with the Rule. *Our recommendation is to perform a survey of specialty pharmacies for their drug acquisition costs.* This may necessitate a separate and more comprehensive cost of dispensing study for this population of providers due to their assertion of higher business costs than retail community pharmacies.

Shifting reimbursement for specialty drugs to AAC rates would lead to cost savings compared to the current specialty ingredient reimbursement of AAC+8%. Since the proposed covered outpatient drug rule does not allow for reimbursement above the AAC, the conclusion is that reimbursement for specialty drugs will need to decrease to comply with the rule. An evaluation of the ingredient reimbursement for specialty drug claims would also necessitate an evaluation of the dispensing fee. The Department would need to weigh its options for a change to its dispensing fee for specialty drug claims, particularly whether a different dispensing fee is required for such claims.

Provider Help Desk

CMS will provide a help desk to support the NADAC, but the scope of services will be limited to supporting questions with regards to the survey process and general understanding of the benchmark. It will not address concerns with individual claims.

As previously discussed, there will be covered outpatient drugs that will not have a NADAC rate. Therefore, DHMH will need to plan for addressing provider concerns with claims for drugs without an assigned NADAC. Even if the State decides to utilize a WAC-based reimbursement rate to produce reimbursement rates for drugs without a NADAC, there will still be drugs that do not have a reimbursement rate. Considerations that the State will need to make include:

- Is it acceptable to hold a claim from processing while the provider is directed to contact a help desk?
- Can the current claims processing help desk address this area of need or does the State need to consider hiring additional help?
- Does the State wish to backdate NADAC rate changes to allow providers to reprocess claims at the updated NADAC rate?

Based on our experience providing help desk services for state-level AAC programs, Myers and Stauffer LC has the expertise, procedures, and trained personnel to provide a help desk for the State if it utilizes the NADAC. The scope of services would include: addressing provider inquiries, performing research to validate drug price changes, establishing AAC reimbursement rates for drugs without a NADAC or WAC, transmitting rates to the claims processing contractor, and publishing AAC rates on a state-specific website.

2. NADAC Reimbursement Checklist

- ✓ Plan for stakeholder involvement in the planning stages of the reimbursement change
- ✓ Develop alternative reimbursement methodology for drugs without a NADAC
- ✓ Update results of previous cost of dispensing survey and select a dispensing fee to employ with the NADAC
- ✓ Settle on reimbursement methodology
- ✓ Draft State Plan Amendment, Administrative Code, and Provider Manual
- ✓ Ensure claims processing contractor has program changes in place to apply new reimbursement methodology
- ✓ Obtain vendor to maintain help desk to address state -level claims for drugs without a rate and to handle provider issues with individual NADAC rates
- ✓ Ensure claims processing contractor and help desk vendor develop a communications plan prior to any reimbursement transition to send rates for drugs without NADACs for other alternative rates

3. Other State Medicaid Programs Utilizing Average Acquisition Cost Reimbursement

Table 5: Other State Medicaid Programs Utilizing Average Acquisition Cost Reimbursement

State	Ingredient Cost	Dispensing Fee
Alabama ¹	AAC+0%	\$10.64
Colorado ¹	AAC+0% for non-rural AAC+variable % for rural	Tiered based on total dispensing volume (range: \$9.31 - \$13.40)
Delaware ²	NADAC+0%	\$10.00
Idaho ¹	AAC+0%	Tiered based on total dispensing volume (range: \$11.51 - \$15.11)
Iowa ¹	AAC+0%	\$10.12
Louisiana ¹	AAC+0%	\$10.51
Oregon ¹	AAC+0%	Tiered based on total dispensing volume (range: \$9.68 - \$14.01)

Note 1: Information presented in table is based upon CMS-approved state plan amendments.

Note 2: Delaware Medicaid began reimbursing pharmacy claims based upon NADAC as of April 1, 2014. A State Plan Amendment documenting this change in reimbursement has not been approved by CMS at the time of the finalization of this report.

4. Analysis Details

Table 6: Fiscal Impact Due to Change in Drug Ingredient Reimbursement Methodology

	Number of NDCs	Annual Units Dispensed	Estimated Annual Expend with Current Reimbursement Methodology	Estimated Annual Expend with Proposed Reimbursement Methodology	Annualized Estimated Ingredient (Savings)/Costs
Brand	1,353	27,346,496	\$282,296,204	\$261,435,500	(\$20,860,704)
Generic	8,350	149,391,692	\$41,624,972	\$41,759,052	\$134,080
OTC Insulin	17	39,320	\$514,196	\$311,812	(\$202,384)
Total	9,720	176,777,508	\$324,435,372	\$303,506,364	(\$20,929,008)

Notes:

- Current reimbursement methodology is defined as the following:
 For brand products - EAC (the lower of AWP - 12% , DP+ 8% WAC + 8%, and U&C).
 For generic products - The lower of EAC, FUL, and SMAC.
 For OTC insulin products - The lower of EAC and SMAC
- Proposed reimbursement methodology is defined as NADAC. If no NADAC, then WAC + 0%. NDCs without a NADAC or WAC were excluded from this analysis.
- Maryland claims data used for analysis is based upon units dispensed between December 1, 2012 and February 28, 2013, then multiplied by four. The claims data includes both retail pharmacy and nursing home pharmacy data. Analysis is limited to those NDCs included in claims data set.
- Analysis excludes blood factor, DME, nutritional, prophylactic and supply products.
- Published pricing is current as of May 23, 2013.
- NADAC current as of May 23, 2013 deliverable files.
- MD SMAC current as of May 2013 web posting.

Table 7: Fiscal Impact Due to Change in Dispensing Fee (DF)

	DF paid for Year (a)	Claim Count for Year (b)	Proposed DF (c)	Proposed Annual DF Costs (d = b x c)	Estimated Increase in Costs due to DF Change (year) (e = d - a)
Retail Pharmacy	\$10,142,268	2,939,856	\$10.49	\$30,839,089	\$20,696,821
Nursing Home	\$850,956	234,288	\$10.49	\$2,457,681	\$1,606,725
Total	\$10,993,224	3,174,144		\$33,296,770	+\$22,303,546

Notes:

- Current reimbursement methodology is defined as the following:
 For non-preferred brand products - dispensing fee of \$2.56
 For generic and preferred brand products - dispensing fee of \$3.51
 For brand products dispensed by nursing home pharmacies – dispensing fee of \$3.51
 For generic products dispensed by nursing home pharmacies – dispensing fee of \$4.46
- Modeled reimbursement methodology is defined as dispensing fee of \$10.49 for all claims.
- Maryland claims data used for analysis is based upon units dispensed between December 1, 2012 and February 28, 2013, then multiplied by four. The claims data include both retail pharmacy and nursing home pharmacy data. Analysis is limited to those NDCs included in claims data set.
- Analysis excludes blood factor, DME, nutritional, prophylactic and supply products.

Table 8: Net Fiscal Impact due to Change in Reimbursement Methodology (Drug Ingredient and Dispensing Fee)(State and Federal dollars)

	Estimated Annualized (Savings)/Costs
Net Ingredient Fiscal (Savings)/Costs	(\$20,929,008)
Net Dispensing Fee Fiscal (Savings)/Costs	\$22,303,546
Total Estimated Fiscal Impact Due to Change in Reimbursement Methodology	+\$1,374,538

Table 9: Fiscal Impact Due to Inclusion of AMP-based FULs in NADAC Drug Ingredient Reimbursement Methodology

	Estimated Annual Expend with NADAC without FULs Reimbursement Methodology	Monthly AMP-based FULs within NADAC Reimbursement Methodology		3-Month Rolling AMP-based FULs within NADAC Reimbursement Methodology	
		Estimated Annual Expend with Monthly AMP-based FULs within NADAC Reimbursement Methodology	Annualized Estimated Ingredient (Savings)/Costs	Estimated Annual Expend with 3-Month Rolling AMP-based FULs within NADAC Reimbursement Methodology	Annualized Estimated Ingredient (Savings)/Costs
Brand	\$261,435,500	\$261,435,500	N/A	\$261,435,500	N/A
Generic	\$41,759,052	\$39,653,448	(\$2,105,604)	\$39,539,288	(\$2,219,764)
OTC Insulin	\$311,812	\$311,812	N/A	\$311,812	N/A
Total	\$303,506,364	\$301,400,760	(\$2,105,604)	\$301,286,600	(\$2,219,764)

Note: Brand drugs were not impacted in this analysis since FUL rates typically do not apply to brand drugs. OTC insulins were not impacted in this analysis due to the lack of Current and AMP-based FULs for OTC insulin products.

Table 10: Price Coverage Analysis

	Number of NDCs	Reported Annual Expenditures	Percent of Expenditures	Annual Claims Counts in Claims table	Percent of Claims
Have NADAC	9,093	\$301,032,485	95.6%	3,125,208	98.7%
Have no NADAC, but have WAC *	954	\$13,738,490	4.4%	37,428	1.2%
Have no NADAC or WAC	147	\$274,656	0.1%	3,744	0.1%
Total NDCs with reported claims data	10,194	\$315,045,631	-	3,166,380	-

Notes:

* This group of NDCs represents a large percent of total units dispensed. Over 80% of these products are fluid or semi-fluid products that are not usually eligible for a NADAC rate. (i.e., nutritional and blood factor products).

- Maryland claims data used for analysis is based upon units dispensed between December 1, 2012 and February 28, 2013, then multiplied by four. The claims data include both retail pharmacy and nursing home pharmacy data. Analysis is limited to those NDCs included in claims data set.

- NADAC and WAC rates are current as of May 23, 2013.